AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS:

1. (Currently Amended) A pharmaceutical composition comprising a complex cladribine-cyclodextrin complex which is an intimate amorphous admixture consisting of (a) an amorphous inclusion complex of cladribine with ~~an~~ the amorphous cyclodextrin hydroxypropyl-β-cyclodextrin and (b) amorphous free cladribine associated with said amorphous cyclodextrin as a non-inclusion complex, formulated into a solid oral dosage form, said composition comprising no significant amount of free crystalline cladribine therein, said composition having a weight ratio of cladribine to said amorphous cyclodextrin of from about 1:10 to about 1:16.

2. (Previously Presented) The pharmaceutical composition according to Claim 1, wherein the complex cladribine-cyclodextrin complex is saturated with cladribine.

3-7. (Cancelled))

8. (Currently Amended) The composition according to ~~Claim 7~~ Claim 1, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:14.

9. (Currently Amended) The composition according to ~~Claim 7~~ Claim 1, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:11.

10. (Cancelled)

11. (Currently Amended) The composition according to Claim 2, wherein the approximate molar ratio of cladribine to said amorphous cyclodextrin corresponds to a point located on the curve of a phase solubility diagram for saturated complex cladribine-cyclodextrin complexes, said curve defining complex saturated complexes of cladribine in varying concentrations of the cyclodextrin.

12. (Previously Presented) The composition according to Claim 1, wherein from about 30 to about 40 percent by weight of the cladribine is in the inclusion complex (a) and from about 70 to about 60 percent by weight of the cladribine is in the non-inclusion complex (b).

13. (Withdrawn and Currently Amended) A method for enhancing the oral bioavailability of cladribine comprising orally administering to a subject in need thereof a pharmaceutical composition comprising a complex cladribine-cyclodextrin complex which is an intimate amorphous admixture consisting of (a) an amorphous inclusion complex of cladribine with ~~an~~ the amorphous cyclodextrin hydroxypropyl-β-cyclodextrin and (b) amorphous free cladribine associated with said amorphous cyclodextrin as a non-inclusion complex, formulated into a solid oral dosage form, said composition comprising no significant amount of free crystalline cladribine therein, said composition having a weight ratio of cladribine to said amorphous cyclodextrin of from about 1:10 to about 1:16.

14. (Withdrawn) The method according to Claim 13, wherein the complex cladribine-cyclodextrin complex is saturated with cladribine.

15-19. (Cancelled)

20. (Withdrawn and Currently Amended) The method according to ~~Claim 19~~ Claim 13, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:14.

21. (Withdrawn and Currently Amended) The method according to ~~Claim 19~~ Claim 13, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:11.

22. (Cancelled)

23. (Withdrawn and Currently Amended) The method according to Claim 14, wherein the approximate molar ratio of cladribine to said amorphous cyclodextrin corresponds to a point located on the curve of a phase solubility diagram for saturated complex cladribine-cyclodextrin complexes, said curve defining complex saturated complexes of cladribine in varying concentrations of the cyclodextrin.

24. (Withdrawn) The method according to Claim 13, wherein from about 30 to about 40 percent by weight of the cladribine is in the inclusion complex (a) and from about 70 to about 60 percent by weight of the cladribine is in the non-inclusion complex (b).

25. (Withdrawn and Currently Amended) A method for the treatment of symptoms of a cladribine-responsive condition in a subject suffering from said symptoms comprising orally administering to said subject a pharmaceutical composition comprising a complex cladribine-cyclodextrin complex which is an intimate amorphous admixture consisting of (a) an amorphous inclusion complex of cladribine with ~~an~~ the amorphous cyclodextrin hydroxypropyl-β-cyclodextrin and (b) amorphous free cladribine associated with said amorphous cyclodextrin as a non-inclusion complex, formulated into a solid oral dosage form, said composition comprising no significant amount of free crystalline cladribine therein, said composition having a weight ratio of cladribine to said amorphous cyclodextrin of from about 1:10 to about 1:16.

26. (Withdrawn) The method according to Claim 25, wherein the complex cladribine-cyclodextrin complex is saturated with cladribine.

27. (Withdrawn) The method according to Claim 25, wherein the cladribine-responsive condition is selected from the group consisting of multiple sclerosis, rheumatoid arthritis and leukemia.

28. (Withdrawn) The method according to Claim 27, wherein the cladribine-responsive condition is multiple sclerosis.

29-31. (Cancelled)

32. (Withdrawn and Currently Amended) The method according to ~~Claim 31~~ Claim 25, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:14.

33. (Withdrawn and Currently Amended) The method according to ~~Claim 31~~ Claim 25, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:11.

34. (Cancelled)

35. (Withdrawn) The method according to Claim 25, wherein from about 30 to about 40 percent by weight of the cladribine is in the inclusion complex (a) and from about 70 to about 60 percent by weight of the cladribine is in the non-inclusion complex (b).

36.-55. (Cancelled)

56. (Currently Amended) A complex cladribine-cyclodextrin complex which is an intimate amorphous admixture consisting of (a) an amorphous inclusion complex of cladribine with ~~an~~ the amorphous cyclodextrin hydroxypropyl-β-cyclodextrin and (b) amorphous free cladribine associated with said amorphous cyclodextrin as a non-inclusion complex, said complex cladribine-

cyclodextrin complex having a weight ratio of cladribine to said amorphous cyclodextrin of from about 1:10 to about 1:16.

57. (Previously Presented) The complex cladribine-cyclodextrin complex according to Claim 56, saturated with cladribine.

58-62. (Cancelled)

63. (Currently Amended) The complex cladribine-cyclodextrin complex according to ~~Claim 62~~ Claim 56, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:14.

64. (Currently Amended) The complex cladribine-cyclodextrin complex according to ~~Claim 62~~ Claim 56, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:11.

65. (Cancelled)

66. (Previously Presented) The complex cladribine-cyclodextrin complex according to Claim 56, wherein from about 30 to about 40 percent by weight of the cladribine is in the inclusion complex (a) and from about 70 to about 60 percent by weight of the cladribine is in the non-inclusion complex (b).

67. (Withdrawn and Currently Amended) A process for the preparation of a complex cladribine-cyclodextrin complex as claimed in Claim 56, which comprises the steps of:

(i) combining cladribine and ~~an~~ the amorphous cyclodextrin in water at a temperature of from about 45 to about 80°C and maintaining said temperature for a period of from about 6 to about 24 hours;

(ii) cooling the resultant aqueous solution to room temperature; and

(iii) lyophilizing the cooled solution to afford an amorphous product.

68. (Withdrawn) A process according to Claim 67, further comprising a filtration step following step (ii).

69. (Withdrawn) A process according to Claim 67, wherein step (i) is performed at a temperature of from about 45 to about 60°C.

70. (Withdrawn) A process according to Claim 67, wherein step (i) is performed at a temperature of from about 45 to about 50°C.

71. (Withdrawn) A process according to Claim 69, wherein step (i) is performed with stirring.

72. (Withdrawn) A process according to Claim 71, wherein step (i) is performed for a period of from about 6 to about 9 hours.

73. (Withdrawn) A process according to Claim 67, wherein step (ii) is performed for a period of from about 6 to about 9 hours.

74. (Withdrawn) A process according to Claim 67, wherein step (iii) comprises an initial freezing stage in which the solution is cooled to from about -40 to about -80° C, and held at said temperature for a period of from about 2 to about 4 hours.

75. (Withdrawn) A process according to Claim 74, wherein, in the initial freezing stage of step (iii), the solution is cooled to about -45°C.

76. (Withdrawn) A process according to Claim 67, wherein 12.00 parts by weight of cladribine and 172.50 parts by weight of hydroxypropyl-β-cyclodextrin are introduced in step (i).

77. (Withdrawn) A process according to Claim 67, wherein 16.35 parts by weight of cladribine and 172.50 parts by weight of hydroxypropyl-β-cyclodextrin are introduced in step (i).

78. (Withdrawn) A process according to Claim 76, wherein 825 parts by volume of water are introduced in step (i).

79. (Withdrawn) A process according to Claim 67, wherein the lyophilization step (iii) comprises:

(a) an initial freezing stage in which the complexation solution is brought to from about -40°C to about -80°C for approximately 2 to 4 hours;

(b) a primary drying stage at about -25°C for approximately 80 to 90 hours; and

(c) a secondary drying stage at about 30°C for approximately 15 to 20 hours.

80. (Withdrawn) A process according to Claim 79, wherein stage (a) of the lyophilization is conducted at about -45°C for approximately 3 to 4 hours.

81. (Withdrawn) A process according to Claim 79, wherein stage (b) of the lyophilization is conducted under a pressure of about 100 mTorr.

82. (Currently Amended) A pharmaceutical composition <u>according to Claim 1</u> obtainable by a process comprising the steps of:

(i) combining cladribine and ~~an~~ <u>the</u> amorphous cyclodextrin <u>hydroxypropyl-β-cyclodextrin</u> in water at a temperature of from about 45 to about 80°C and maintaining said temperature for a period of from about 6 to about 24 hours;

(ii) cooling the resultant aqueous solution to room temperature;

(iii) lyophilizing the cooled solution to afford an amorphous product; and

(iv) formulating the amorphous product into a solid oral dosage form.

83. (Original) A pharmaceutical composition according to Claim 82, wherein the process further comprises a filtration step following step (i) or (ii).

84. (Previously Presented) A pharmaceutical composition according to Claim 82, wherein step (i) of the process is performed at a temperature of from about 45 to about 60°C.

85. (Previously Presented) A pharmaceutical composition according to Claim 82, wherein step (i) of the process is performed at a temperature of from about 45 to about 50°C.

86. (Previously Presented) A pharmaceutical composition according to Claim 84, wherein step (i) of the process is performed with stirring.

87. (Original) A pharmaceutical composition according to Claim 86, wherein step (i) of the process is performed for a period of from about 6 to about 9 hours.

88. (Previously Presented) A pharmaceutical composition according to Claim 82, wherein step (ii) of the process is performed for a period of from about 6 to about 9 hours.

89. (Previously Presented) A pharmaceutical composition according to Claim 82, wherein step (iii) comprises an initial freezing stage in which the solution is cooled to from about -40 to about -80°C, and held at said temperature for a period of from about 2 to about 4 hours.

90. (Original) A pharmaceutical composition according to Claim 89, wherein, in the initial freezing stage of step (iii), the solution is cooled to about -45°C.

91. (Previously Presented) A pharmaceutical composition according to Claim 82, wherein 12.00 parts by weight of cladribine and 172.50 parts by weight of the hydroxypropyl-β-cyclodextrin are introduced in step (i) of the process.

92. (Previously Presented) A pharmaceutical composition according to Claim 82, wherein 16.35 parts by weight of cladribine and 172.50 parts by weight of the hydroxypropyl-β-cyclodextrin are introduced in step (i) of the process.

93. (Previously Presented) A pharmaceutical composition according to Claim 91, wherein 825 parts by volume of water are introduced in step (i) of the process.

94. (Previously Presented) A pharmaceutical composition according to Claim 82, wherein the lyophilization step (iii) of the process comprises:

(a) an initial freezing stage in which the complexation solution is brought to from about -40°C to about -80°C for approximately 2 to 4 hours;

(b) a primary drying stage at about -25°C for approximately 80 to 90 hours; and

(c) a secondary drying stage at about 30°C for approximately 15 to 20 hours.

95. (Original) A pharmaceutical composition according to Claim 94, wherein stage (a) of the lyophilization is conducted at about -45°C for approximately 3 to 4 hours.

96. (Previously Presented) A pharmaceutical composition according to Claim 94, wherein stage (b) of the lyophilization is conducted under a pressure of about 100 mTorr.

97. (Previously Presented) A pharmaceutical composition according to Claim 82, wherein the formulation step (iv) of the process comprises blending the complex with magnesium stearate and compressing into tablets.

98. (Original) A pharmaceutical composition according to Claim 97, wherein magnesium stearate is pre-mixed with sorbitol powder before blending with the complex.